

<b>Title:</b>  <b>Formatting of Quality Procedures/Work Instructions</b>	<b>Number:</b>  00-0000-052-02	<b>Revision Number:</b>  0	<b>Date Effective:</b>  3/11/97
	<b>Prepared By:</b>  <b>K. Colville, J. Kozul</b>	<b>Approved By:</b>  <b>Sondra D. Gutkind</b>	<b>Page:</b>  <b>1 of 4</b>

## **5.0 Purpose**

5.0 To provide a consistent method for the Division for formatting quality procedures and work instructions.

## **5.1 Scope**

5.1 This procedure applies to Pilot Programs entering the Division Management System (DMS) and certified Pilot Programs when revising or generating new documentation.

## **5.2 Responsibilities**

5.2.1 The Pilot Program Department Head (PPDH) for the new pilot programs is responsible for identifying and writing quality procedures and work instructions.

5.2.2 The PPDH for certified pilot programs is responsible for implementing this procedure when revising or generating new documentation.

5.2.3 The Division Document Control Administrator (DDCA) is responsible for providing title block boilerplates and assistance in formatting of quality procedures and work instructions.

## **5.3 Definitions**

5.3.1 Quality procedure: A procedure that outlines the major processes that are accomplished in the pilot program. Where appropriate, quality procedures must refer to their applicable work instructions.

5.3.2 Work instruction: An instruction that details the smaller processes needed to accomplish the quality procedures.

5.3.3 Records: Written statements of data and facts characterizing specific events that pertain to specific personnel, products, processes, etc..

5.3.4 Documents: Contains information and instructions.

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## 5.4 Procedure

5.4.1 The PPDH for new pilot programs, or designee, shall identify and write quality procedures and work instructions for the Pilot Program. The PPDH for certified pilot programs, or designee, shall reformat their existing quality procedures/work instructions as revisions are being made and use this format when generating new quality procedures/work instructions. The format is as follows:

5.4.1.1 The **TITLE BLOCK** header on each page of the quality procedure or work instruction shall contain the title, quality procedure/work instruction number, revision number, effective date, originator's name, approver's name, and page number.

5.4.1.1.1 Quality procedures/work instructions shall be numbered as follows:

<b>XX</b>	-	<b>XXXX</b>	-	<b>XXX</b>	-	<b>XX</b>
00		4 digit code the quality procedure/work instruction applies to		ISO9001 element (01-20), number in tier level(3,4)		Procedure the element (01, 02, etc)

5.4.1.2 The **PURPOSE** section shall indicate the intent of the quality procedure/work instruction.

5.4.1.3 The **SCOPE** section shall indicate which codes/departments or functions the quality procedure/work instruction applies.

5.4.1.4 The **RESPONSIBILITIES** section shall indicate the responsibilities of all personnel involved in the quality procedure/work instruction.

5.4.1.5 The **DEFINITIONS** section shall define any words that will clarify the quality procedure/work instruction in this section.

5.4.1.5.1 If no definitions are needed, "None" shall be listed.

5.4.1.6 The **PROCEDURE** section shall describe the actual process to accomplish the quality procedure/work instruction. The procedure shall be written so that the personnel in the scope will be able to understand and perform the process.

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5.4.1.7 The **REFERENCE** section shall list any references used within the quality procedure/work instruction.

5.4.1.7.1 If references were not used, "None" shall be listed.

5.4.1.8 The **RECORDS** section shall list the Quality records that are the results of the quality procedure/work instruction.

5.4.1.8.1 Each quality record must also be listed in the Quality Records procedure where persons responsible, location, retention time, etc. are listed.

5.4.1.8.2 If no quality records were generated as a result of the quality procedure/work instruction, "None" shall be listed.

5.4.1.9 The **ATTACHMENTS** section shall list any attachments that accompany the quality procedure/work instruction.

5.4.1.9.1 If no attachments accompany the procedure/work instruction, "None" shall be listed.

5.4.1.10 Quality procedure and work instruction sections shall be numbered as follows:

Purpose:	XX.0
Scope:	XX.1
Responsibilities:	XX.2
Definitions:	XX.3
Procedure:	XX.4
References:	XX.5
Records:	XX.6
Attachments:	XX.7

XX is the ISO element number (1-20). Each subparagraph of the section shall be numbered sequentially by adding another period and the appropriate number (XX.X.1, XX.X.2, etc).

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5.4.1.11 For uniformity of appearance, it is recommended that point font size of the text for all quality procedures and work instructions be 12.

## **5.5 References**

None

## **5.6 Records**

None

## **5.7 Attachments**

None